



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 28 1999

SEP 28 1999

Mr. Wayne Reis
President
E'OLA International
3879 South River Road
St. George, Utah 84790

Dear Mr. Reis:

This is in response to your letter to the Food and Drug Administration (FDA) dated September 3, 1999, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that E'OLA International is making the following claims, among others, for the product "Meta-CLA:"

"...normalize cholesterol levels by lowering the bad or LDL cholesterol..."

"...normalization of cholesterol levels..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 300

Page 2 - Mr. Wayne Reis

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS- 155 (Foret)

HFS- 165 (Wilkening)

HFS-456 (tile, r/f)

HFS-450 (r/f, file)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

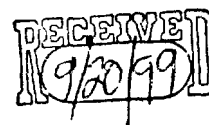
f/t:HFS-456:rjm:9/27/99:docname:67235.adv:disc40



67235

September 3, 1999

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, SW.
Washington D.C. 20204



Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. & 343® and 21 CFR & 101.93

Dear Dr. Yetley:

E'OLA International, in accordance with 21 U.S.C. & 3438 and 21 CFR & 101.93, hereby submits an original and two copies of its notification of its product marketing with the statement presented below. E'OLA International retains scientific documents supporting the statements.

1. Supplement Brand Name: **Meta-CLA**
2. Supplemental Ingredient(s) that is the subject of the statement: **Conjugated Linoleic Acid**
3. Text Of Statements Of Nutritional Support:
 - A. **CLA inhibits the body's ability to store fat.**
 - B. **CLA stimulates the enzyme hormone sensitive lipase which pulls fat out of storage in the fat cells and stimulates the manufacture of that fat into energy.**
 - C. **CLA has been shown to increase lean muscle tissue.**
 - D. **CLA helps normalize cholesterol levels by lowering the bad or LDL cholesterol and raising the good or HDL cholesterol.**
 - E. **Powerful immune system stimulate.**
 - F. **Normalization of nerve and muscle cell wall function, stimulating the growth of lean muscle, significant improvement in energy levels, normalization of cholesterol levels, and a major improvement in the strength and potency of the immune system.**

- G. **Improve insulin function.**
- H. **Reduction in whole body fat percentages.**

In accordance with 21 U.S.C. & 343® and 21 CFR & 101.930, each of the above statements will be followed by an asterisk that will cross-reference to another asterisk on the very same panel or page next to which the following statement will appear in the box in bold face type:
“These statements have not been evaluated by the Food and Drug Administration. The product is not intended to diagnose, treat, cure or prevent any disease.”

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'Wayne Reis', with a stylized flourish extending to the right.

Wayne Reis
President
E'OLA® International